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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,758	05/01/2001	Alex Liu	EP01-001C	4859
23500	7590	12/05/2005	EXAMINER	
PATENT DEPT EXELIXIS, INC. 170 HARBOR WAY P.O. BOX 511 SOUTH SAN FRANCISCO, CA 94083-0511			MORAN, MARJORIE A	
		ART UNIT	PAPER NUMBER	1631
DATE MAILED: 12/05/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,758	LIU ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11-21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 11, 15-21, and 23-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/05 has been entered. Claims 1-9, 11-21, 23-25 are pending.

All rejections and objections not reiterated below are hereby withdrawn in view of the claim amendments filed 9/6/05. Applicant is advised that withdrawn rejections may be reinstated upon amendment canceling limitations with regard to recessive mutations/mutagens.

Election/Restrictions

Claims 12-14 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/19/03.

An action on the merits of claims 1-9, 11, 15-21 and 23-25, as they read on the elected species of altered resistance to an herbicide, follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11, 15-21, and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

An insertional recessive mutagen, as recited in claims 1, 2, 20, and 23-24, is new matter. An insertional recessive mutagen which is capable of gain of function, as recited in claim 1, is new matter. A step of rescuing DNA flanking an insertional recessive mutagen from a T1 generation plant, as recited in claim 23, is new matter. An insertional recessive mutagen which results in a **dominant** mutation, as recited in claim 24, is new matter.

In the response filed 9/6/05, applicant does not point to support anywhere in the originally filed disclosure for the newly recited amendments. The original claims recited an insertional mutagen, but did not limit the insertional mutagen to be either dominant or recessive. Original claims 22 and 24 limited a mutant trait to be a dominant mutant trait, but did not limit the mutagen causing the trait to be dominant. None of the original claims recited a recessive mutant trait or recessive mutagen or a mutagen which causes recessive traits. The originally filed specification, on page 3, lines 26-29, discloses that one aspect of the invention is methods for confirming association of dominant mutant traits with an inheritance pattern or specific gene. Page 6 of the

originally filed specification discloses that an insertional mutagen may **cause a** dominant or recessive mutant trait (lines 9-13), but is silent with regard to whether the mutagen itself is dominant or recessive. Page 6 further discloses that recessive mutant traits are generally loss-of-function whereas dominant traits are generally gain-of-function (lines 13-16 and 28-30). While page 6 does disclose that insertional mutagens may generate both loss- and gain-of-function mutations, it is noted that these may be separate mutations, as supported by p. 31, that insertional mutagens may cause mutations in a plurality, or nearly all, genes. There is no disclosure anywhere for a gain-of-function mutation associated with a recessive mutant trait or any sort of "recessive mutagen." For these reasons, an insertional recessive mutagen, an insertional recessive mutagen which is capable of gain of function, as and an insertional recessive mutagen which results in a **dominant** mutation, are new matter.

The original specification, on page 28, teaches that mutant traits observed in T2 plants, **but not in T1 plants**, may be recessive. Thus, although a step of identifying a candidate gene by rescuing DNA flanking an insertional mutagen from a "subsequent generation" plant where the mutation is recessive MIGHT be supported by the totality of the disclosure, a similar method wherein a gene causing a recessive mutation is identified by rescuing DNA from **T1 plant** is not. For this reason, a step of rescuing DNA flanking an insertional recessive mutagen from a T1 generation plant is new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 limits an insertional mutagen to be recessive and a mutant trait to be dominant, which is confusing. Claim 25 depends from claim 24 and also recites a "dominant mutant phenotype" in step (p). As set forth above, the specification provides support for insertional mutagens which generate dominant or recessive mutant traits, but not for an "insertional recessive mutagen". The term "insertional recessive mutagen" is not specifically defined anywhere. It may be that applicant intends an "insertional recessive mutagen" to be an insertional mutagen which generates a recessive mutant trait. If so, then the combined limitations of an "insertional recessive mutagen" with the dominant mutant trait and dominant mutant phenotype of claims 24 and 25, respectively, is nonsensical.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

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272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/28/05